

### **Remarks**

This is in reply to the official action of June 8, 2009.

In view of the Examiner's comments it is assumed that the Applicants need to take no further action with respect to the restriction/election requirement. The Applicants elected the particular lipid conjugate in the prior response, i.e. specific lipid conjugate galactocerebrosides.

Further claims 13-15 and 17-36 have been acted on by the Examiner, the only withdrawn claim being claim 16.

The traverse is maintained because the Examiner's statement as to why there is no unity of invention is insufficient. The Examiner says that a special technical feature of a "cosmetic composition comprising a lipid conjugate consisting of sphingolipids, galactolipids, and mixtures thereof, and a fluorocarbon" on the basis of an obviousness rejection based upon Unger, Felke et al and Schmidt. This is improper in that the present invention is not obvious in view of the cited references for the reasons subsequently discussed. For this reason it is clear that claim 16 should be rejoined.

Claims 33-36 have been rejected under 35 U.S.C. 112 for lack of antecedent basis "1,2-propylene glycol, glycerin, sphingolipid-oil/wax solution, PEG 75-shea butter, perfluorodecalin and water.

This rejection is improper and should be withdrawn.

Parent claim 13 uses the term "comprises" and is thus open ended to additional components, e.g. as listed in dependent claims 33-36. With the term "comprises" there is no need to list alcohol or PEG-75 Shea Butter or water.

Claims 13-15 and 17-20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (U.S. Patent 5,705,187) and Felke et al (WO 95/20945) and Schmidt (U.S. Patent 5,776,470). Unfortunately this rejection is incomprehensible, should be withdrawn and a new non-final official action should be provided. Neither the inventors nor assignee on WO 95/20945 has a name Felke or anything close to that name. Further, supposed disclosure cited by the Examiner is not found in WO 95/20945. Therefore, except for claims 33-36 there is no comprehensible rejection of the claims.

Further, for the reasons previously given, the 35 U.S.C. 112 rejection discussed above, with respect to claims 33-36 is clearly improper. This rejection is improper and should be withdrawn.

Nevertheless, an attempt will be made to answer the rejections to the extent they might be understood.

The Unger reference is directed to a composition comprising “stable” vesicles containing a gas, i.e. a free gas, that is injected intravenously to provided an enhanced ultra sound image. (see e.g. Unger column 3, lines 4-62, and column 5, lines 1-46; column 22, lines 8-11) Toward this end, Unger requires a strong vesicle stabilizer. This is completely contrary to and **teaches away from the present invention** where the vesicles are formed to release oxygen into the skin instead of retaining a gas as taught by Unger. (See e.g. Unger Column 3, lines 65-67 and all of column 4) (See the present specification page 7, paragraph [0022]. Unger does not disclose or suggest a vesicle having a vesicle membrane of sphingolipids, galactolipids, or mixtures thereof that is less stable than a vesicle with a phospholipids membrane wherein the vesicle will release oxygen to tissue upon penetration of the skin.

It should also be pointed out that the Examiner picked and chose separate disclosures within Unger based entirely upon the Applicant’s disclosure.

Unger discloses no fewer than 50 possible lipid type materials for forming a membrane and discloses no fewer than 50 possible stabilizers as Unger requires. The permutations for making a selection of components within Unger using only those two components is thus more than 2500 and when other components taught or suggested by Unger are included, there are literally millions of possibilities. It was simply not obvious to one skilled in the art to pick a combination of various components within Unger to obtain the present invention especially since the picking of desired components would be exactly contrary to reasons given by Unger for making particular choices, i.e. high stability of vesicle containing gas for purposes of imaging contrary to the present invention where such high stability is detrimental to release of oxygen to tissues. **Unger thus clearly does not disclose or suggest the critical combination of components of the presently claimed invention.** Any such combination could only be made by

unsupported and improper hindsight after first learning about the invention from the present application.

The only references of record that contain anything close to the disclosure to the non-existent Felke reference are German, EP and PCT references to Gross et al and one to Long where **phospholipid** compositions for carrying oxygen in conjunction with a fluorocarbon are described. As previously discussed, phospholipids vesicles are very stable and thus do not readily release oxygen to surrounding tissue as is the case with sphingolipids and galactolipids in accordance with the presently claimed invention. Again, as previously discussed, stable phospholipids vesicles have previously been desired as described in Unger et al. but are undesirable in the present invention. The use of relatively unstable sphingolipids and galactolipids to form vesicles in accordance with the present invention is not suggested by any of the cited references alone or in any combination.

Reference may be had, in the present application, to the Background of the Invention, The Brief Description of the Invention, Paragraph [0022] and the Examples and Table in the Detailed Description of the Invention, detailing the desirability of vesicles that will release oxygen upon penetration of the skin.

The cited Schmidt reference does absolutely nothing to cure the critical defects of Unger et al. Schmidt does not even relate to vesicles and certainly does not relate to vesicles having a sphingolipid and/or galactolipid membrane containing a fluorocarbon charged with oxygen and suggests nothing at all concerning improved oxygen transport.

All rejections of other claims, all of which carry the limitations of Claim 13, are defective for the same reasons given above. All remaining rejections rely upon Unger, which is defective for reasons previously discussed and upon Felke, which, if it even exists, is not a reference identified in the record. None of the additionally cited references cure the critical defects presented by Unger and Felke. None of the references suggest anything or any way in which oxygen transport into the skin can be improved by a novel vesicle having a sphingolipid and/or galactolipid membrane containing a fluorocarbon charged with oxygen that readily releases the oxygen when entering the skin.

Amendments to the specification are made to correct inadvertent typographical type errors.

The amendments to the fourth paragraph on page 9 of the specification are supported by original claim 9 (amended claim 30) and by examples 1 and 2 of the original specification.

The amendment to claim 32 (original claim 11) is supported by the first full paragraph on page 10, lines 6-10 of the specification and appeared in the specification as originally filed.

All claims are patentable over the current rejections as previously discussed.

The Examiner is again reminded that the current rejections are fatally defective and a final action may not properly be provided in the next official action.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael L. Dunn", with a long horizontal flourish extending to the right.

Michael L. Dunn  
Registration No. 25330  
CUSTOMER NO. 49003  
Simpson & Simpson, PLLC  
5555 Main Street  
Williamsville, NY 14221-5406  
Telephone No. 716-626-1564

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MLD/MJK